

REMARKS

Claims 1-10 have been canceled without prejudice or disclaimer. Claim 11-18 have been added and therefore are pending in the present application.

In the previous office action, the Examiner objected to the form of the claims and rejected the claims under 35 USC 103. By this amendment, applicants have conformed the claims to customary US practice and therefore have addressed the Examiner's objections.

Applicants also respectfully assert that the pending claims are not obvious in view of Nguyen et al. (US 5,873,462) and Current et al. (US 4,203,518).

First Current et al. does not relate to the field of injection needles. It relates to sewing needles and is therefore not properly combinable with Nguyen et al. Not all needle art is analogous. *C.f. In re Oetiker*, 977 F.2d 1443 (Fed Cir 1992). For example, sewing needle magazines lack a sterility barrier to keep their compartments sterile and require that the needles be handled when inserting and removing them. This, of course, is an unacceptable practice for injection needles, which must remain sterile.

Moreover, it is well-settled law that the proposed modification cannot change the principle of operation of a reference. See MPEP 2143.01, Here, even if a sterility barrier were added to Current et al, there would be no way of removing the sewing needles from the magazine and placing them on a device without handling them. It is necessary for operation of the Current et al. device that the needles be readily inserted and removed by hand, as sewing needles are handled in this manner. In contrast, injection needles should not be touched.

Second, even if Current were properly combinable with Nguyen, Applicants' invention provides an unexpected advantage, i.e. the claimed magazine is useful as a tool to assist in securing injection needles to injection devices. Unexpected results, such as this, are, of course, sufficient to overcome obviousness so long as the references cited do not suggest the unexpected advantage.

Neither Current et al. nor Nguyen et al. suggests the advantage in the presently claimed invention. In fact, Nguyen discloses a magazine that makes it difficult to hold in the palm of a hand. And Current does not disclose using the magazine described therein as a wrench or tool for

mounting needles to another device. Moreover, in Nguyen, the height of the needle magazine would be somewhat greater than the length of the injection needle assemblies. For a standard pen needle having an injection part length of 16 mm, the entire assembly length would be 30 mm, giving a magazine height of more than 40mm. The magazine needs to be placed on a flat surface prior to mounting a needle assembly on an injection device. This set-up provides users who have poor or restrict motor skills problems. Particularly because the user has to typically rotate the injection device two full revolutions, i.e. 720 degrees.

As the Specification of the instant application discloses at page 3, lines 10-20, applicants have surprisingly found that a needle magazine of the claimed configuration provides greater leverage and is useful as a tool for securing needle assemblies to injection devices and that needles can be mounted by rotating the magazine 360 degrees and rotating the injection device 360 degrees in an opposite direction. This eliminates the need for one 720 degree rotation. This unexpected advantage results from the fact that the needle magazine is only slightly larger than the diameter of the needle hubs and therefore allows the needle magazine of the present invention to fit in the palm of a hand. Moreover, as the magazine can be grasped at two opposite points along its circumference and the needle assembly being fastened or unfastened is centered between these two points, leverage is maximized. This allows the needle magazine to be used as a wrench. And since the moment applied is the multiplication of the force used and the length of the lever arm, the needle magazine of the claimed invention now makes it easier for people with limited physical strength or motor control to connect needle assemblies to injection devices. Prior art magazines, such as Nguyen, would not and could not provide this advantage.

Applicants respectfully note that none of the references cited by the Examiner suggest these result are achievable – or are even desirable. This feature is not addressed in any of the cited injection needle magazine art and it is not particularly an advantage within the sewing needle art. Accordingly, absent impermissible hindsight, there would be no motivation to combine the references as the Examiner has done. *See e.g.*, MPEP 2143.01 (fact that references can be combined or modified is not sufficient to establish *prima facie* obviousness).

X. Conclusion

In view of the above, Applicants respectfully submit that all claims are in condition for allowance. Early action to that end is respectfully requested. The Commissioner is hereby authorized to charge any fees in connection with this application, including any fees for extensions of time, and to credit any overpayments to Deposit Account No. 14-1447.

The Examiner should feel free to contact the Applicants attorney by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,



Date: June 10, 2003

Marc A. Began, Reg. No. 48,829
Novo Nordisk Pharmaceuticals, Inc.
100 College Road West
Princeton, NJ 08540
(609) 987-5800



23650

PATENT TRADEMARK OFFICE